REMARKS

Reconsideration of the subject application is respectfully requested.

Claims 13-15, 18-21, and 24-32 were pending as of the Office Action mailing date of January 12, 2009. Applicant amends herein independent claim 13. No new matter has been added by any of the amendments.

In view of MPEP 707.07 that requires the Action to be complete as to all matters, Applicant proceeds under the understanding that the present claims are patentable once patentable distinction is established over the references cited herein.

I. REJECTION UNDER 35 USC 112, 2nd paragraph

Claims 13-32 have been rejected under 35 USC 112, 2nd paragraph. Applicant respectfully traverses this rejection based on currently amended claim 13.

The current invention, as now claimed, is a process that requires:

> … is combined for recrystalizing and the stereoisomer to be isolated in each case is precipitated and obtained in enriched form, wherein for the preparation of those tertiary, basic diastereomer mixtures employed in the quaternization which lead to the abovementioned quaternary diastereomer mixtures
>
> a solvent is selected from the group consisting of branched and unbranched alcohols having one to four carbon atoms, acetone, butanone and acetonitrile in which the diastereomer mixture dissolves readily in said solvent, and said solvent consisting of branched and unbranched alcohols having one to four carbon atoms is preferably methanol, ethanol, or combinations thereof,

> and the stereoisomer to be isolated in each case is precipitated to be obtained in enriched form,
>
> using a second solvent preferably selected from ethyl acetate and/or tert-butyl methyl ether causing crystallization (amended claim 13)

Claim 13 has been amended to clearly set forth the steps in the process. The process provides basic diastereomer mixtures employed in the quaternization which lead to quaternary diastereomer mixtures; the diastereomer mixtures are dissolved in a solvent selected from the group consisting of branched and unbranched alcohols; a stereoisomer is precipitated using a second solvent.

The claimed invention is characterized by the specificity of the suitable solvents for the recrystallization. Additionally, Applicant asserts that process steps are present in the claim. Applicant respectfully asserts the positive steps of "combining," "recrystalizing," and "precipitating," are process steps that have the requisite particularity and distinctness to those with ordinary skill in the art as required by 35 USC 112. Applicant respectfully requests reconsideration and withdrawal of this rejection.

II. Rejection under 35 USC 102(b)

Claims 13-32 have been rejected under 35 USC 102(b) as anticipated by Noe, et al. (U.S. Patent 6,307,060, the '060 patent). Applicant respectfully traverses this rejection. Claim 13 is amended herein.

Claims 13-32 rejection under 35 USC 102(b) as being unpatentable over the Noe '060 patent of record.

The present application specifically sets forth a goal of the present invention by stating:

> the method according to the invention shows marked advantages compared with other conceivable processes for the preparation of said stereoisomer from the respective diastereomer mixture. Thus, in the process according to the invention no additional chiral auxiliaries, which in some cases are very expensive and possibly not accessible at all in larger amounts, are necessary (published application 2006/0167275, paragraph [0048], emphasis added).

The present invention provides a simpler process than that of the Noe '060 patent of record.

The solvents claimed in the subject application distinguish the present invention from the '060 patent because the '060 uses chiral tartaric acid for the separation of the racemate (see Noe, Examples 1 and 3). The present invention differs from this process by providing a simplified process for the preparation of enantiomerically pure glycopyrronium compound. This process would not be obvious to the skilled person, as there are numerous solvents to be used in the process, and the selection of the solvents which can be successfully used in separation the diastereomer mixture are not obvious form any prior art disclosure.

The '060 patent has no disclosure for this process. Applicant reminds the Office:

> "[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where

> there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Claim 13 is respectfully asserted not anticipated by the '060 patent because claim 13 requires, precipitating with branched and unbranched alcohols having one to four carbon atoms, acetone, butanone and acetonitrile; and re-crystallization with a second solvent selected from ethyl acetate and/or tert-butyl methyl ether. Thus the '060 is deficient in failing to have the requisite disclosure to anticipate the claim.

The disclosure in the Noe patent is deficient because it does not disclose the use of the subject claims in its entirety. The Office Action states that 2-butanone is used in the workup of the Noe patent (Office Action, page 2). However, the mere disclosure of this solvent does not anticipate the subject application because, as admitted to in the Office Action, it is in the workup and not an integral step of the separation process. Thus, the mere recitation of 2-butanone fails to disclose exactly what is claimed, as required and set forth above in *Titanium Metals Corp.*

Applicant reminds the Office, anticipation requires more than a mere list of the claimed elements.

> Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim."; W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 U.S.P.Q. (BNA) 303 (Fed. Cir. 1983).

The Noe patent discloses 2-butanone, but does not disclose the required solvents **as arranged as in the claim.**

> A single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art." Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002).

The Noe patent does not have the required disclosure of elements arranged as in the claim, nor does it have the description of the claimed invention of the subject application with sufficient precision to meet the requirements at law establishing anticipation because the Noe patent requires the use of tartaric acid that is contrary to the required compounds of the subject application. The recitation of 2-butanone as well as the explicit teaching to use additional chiral reagents makes the disclosure in the cited Noe patent deficient and does not provide the requisite arrangement of elements and precision to anticipate the pending claims.

Because of the failure of the '060 patent to anticipate the claimed invention, applicant asserts a rejection under 35 USC 102(b) cannot be properly applied.

Applicant respectfully request reconsideration and withdrawal of this rejection.

III. DOUBLE PATENTING

The Office Action, on page 3, as set forth a rejection under the doctrine of obviousness type double patenting. Applicant submits herewith a terminal disclaimer to obviate this rejection.

Based upon the amendments and representations presented herein, Applicant respectfully asserts the application is now in condition for allowance. If the

Examiner believes there any issues that have not been resolved the Examiner is invited to call the undersigned representative who is attorney of record in this case.

If an extension of time is required, petition for extension is herewith made. Any extension fee associated therewith should be charged to Deposit Account Number 12-1099 of Lerner Greenberg Stemer LLP. Please charge any other fees that might be due with respect to Sections 1.16 and 1.17 to Deposit Account Number 12-1099 of Lerner Greenberg Stemer LLP.

Respectfully submitted,

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